K120451

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
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Date February 3rd, 2012

Traditional 510(k) Summary (in accordance with 21 CFR 807.92)

1. Date of Summary

February 3rd, 2012

2. Company

EIZO NANAO CORPORATION
153 Shimokashiwano, Hakusan
Ishikawa 924-8566 Japan

3. Authorized Contact Person

Hiroaki Hashimoto

4. Device Information

- Trade Name/Model: RadiForce RX840-MG
- Common Name: 8MP Color LCD Monitor
- Classification Name: System, Image Processing, Radiological
- Regulation Number: 21 CFR 892.2050, Product Code LLZ

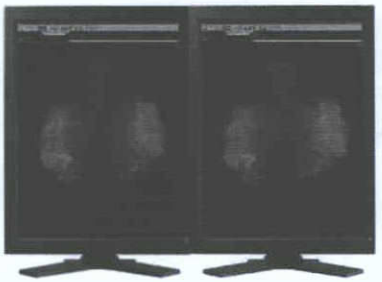
5. Predicate Device

- 5MP Monochrome LCD Monitor, RadiForce GX530 (K112354)

6. Device Description

The RadiForce RX840-MG is a color LCD monitor for viewing medical images including those of mammography. The color panel employs in-plane switching (IPS) technology allowing wide viewing angles. With the matrix size (or resolution) of 4,096 x 2,160 pixels (8MP), the RX840-MG is an alternate replacement for traditional dual head 5MP display installations.

RadiForce RX840-MG



5MP Monochrome Monitors

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used. This helps ensure tone curves even if a display controller or workstation must be replaced or serviced.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce RX840-MG based on several QC guidelines. The RadiCS and its subset, RadiCS LE are included in this 510(k) submission as an accessory to the RadiForce RX840-MG.

7. Intended Use

The RadiForce RX840-MG is intended to be used in displaying and viewing digital images including those of digital mammography for review and analysis by trained medical practitioners.

8. Comparison of Technological Characteristics

The comparison table below enumerates information derived from the product literature of the each device and different technological characteristics are discussed in it:

Attributes	Eizo RadiForce RX840-MG	Eizo RadiForce GX530	Explanation of Differences
Display Performance/Specifications			
Screen technology	**TFT Color LCD Panel (IPS)**	**TFT Monochrome LCD Panel (IPS)**	**Monochrome vs. Color (w/o & w/ color filters). See main text.**
Viewing angle (H, V)	H: 176°, V: 176°	H: 170°, V: 170°	Eizo uses the typical data for very low contrast 10:1 given by the panel manufacturers
Active screen size	817.1 x 430.9 mm (408.05 x 430.9 mm x 2)	337.9 x 422.4mm	The difference of 400 pixels in vertical direction is such a degree that it can be easily negated e.g. by a small amount of panning manipulation or by changing the tool bar setting of the viewer software (location, disappear when the cursor isn't on it etc.)
Resolution	8 MP (4,096 x 2,160) (4MP: 2,048 x 2,160 x 2)	5 MP (2,048 x 2,560)	
Aspect ratio	17 : 9 (8.5 : 9 x 2)	4 : 5	
Pixel pitch	0.1995 x 0.1995 mm	0.165 x 0.165 mm	-
Maximum luminance	700 cd/m^2	1,200 cd/m^2	Smaller maximum luminance value means shorter period during which calibrated luminance can be guaranteed: RX840-MG: 10K hours vs. GX530: 40K hours.
DICOM calibrated luminance	500 cd/m^2	500 cd/m^2	-
Contrast ratio	1000: 1	1200 : 1	Eizo uses typical contrast ratio data provided by panel manufacturers.
Backlighting	**LED**	**CCFL**	**See main text.**

Grayscale Tones	**10-bit: 1,024 from a palette of 4,096 tones 8-bit: 256 from a palette of 4096 tones**	**10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones**	**See main text.**
Luminance non-uniformity compensation	Digital Uniformity Equalizer (DUE)	Digital Uniformity Equalizer (DUE)	-
Video Signal Input			
Input video signals	DVI-D (Dual Link) x 2, DisplayPort x 2	DVI-D (Dual Link) x 1 , DisplayPort x 1	-
Scanning Frequency (H, V)	31 - 140 kHz, 29.5 - 30.5 Hz (2048 x 2160, 1920 x 2160), 59 - 61 Hz, (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	31 - 135 kHz, 24 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 24.5 - 25.5 Hz, 49 - 51 Hz	-
Dot Clock	DVI-D: 310 MHz, DisplayPort: 290 MHz	290 MHz	-
Display controller	Off the shelf	Off the shelf	-
Power Related Specifications			
Power Requirements	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	-
Power Consumption / Save Mode	350 W / Less than 6 W	130 W / Less than 2.5 W	The proposed device consumes more power due to the larger panel size.
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-
Miscellaneous Features/Specifications			
QC software	RadiCS	RadiCS	-
Sensors	Backlight Sensor (BS), Integrated Front Sensor (IFS), Presence Sensor (PS), Ambient Light Sensor (ALS)	Backlight Sensor (BS), Integrated Front Sensor (IFS), Presence Sensor (PS), Ambient Light Sensor (ALS)	-
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
Dimensions w/o stand (W x H x D)	896 x 527 x 157 mm	388 x 496 x 99 mm	Different housing design due to the different panel size.

For the substantial equivalence determination, only the following differences of the technological characteristics need further evidences by performance testing:

- The RadiForce RX840-MG employs a color LCD panel module though the predicate device employs a monochrome LCD panel module.
- The smaller number of gray tones available to calibration of the color display (e.g. to GSDF) than that of the monochrome display may affect calibration accuracy.
- The RadiForce RX840-MG employs an LED backlight though the predicate device employs a CCFL backlight; advantage of the LED backlight is that it is mercury-free, consumes less power and deteriorates more slowly.

9. Performance Testing

The following bench tests were performed on the RadiForce RX840-MG following instructions in Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions:

- Verification of the conformance to DICOM GSDF as specified in *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline)
- Measurement of the angular dependency of luminance response in horizontal, vertical and diagonal directions
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in TG18 guideline
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in TG18 guideline
- Measurement of the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance
- Measurement of display reflections including specular, diffuse and haze components
- Measurement of small-spot contrast ratio
- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- Measurement of noise expressed as noise power spectrum (NPS)
- Measurement of pixel aperture ratio
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in TG18 guideline
- Measurement of temporal response
- Performance data on luminance stability
- The maximum number allowed for each type of pixel defects/faults agreed with the manufacturer from which Eizo buys the LCD panels for RadiForce RX840-MG

The test results showed that the RadiForce RX840-MG has display characteristics equivalent to those of the predicate device, RadiForce GX530 except 4 items, each of which was determined that it would not affect observer's performance. Besides, the display characteristics of the RadiForce RX840-MG meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce RX840-MG.

10. Conclusion

The 8MP Color LCD Monitor, RadiForce RX840-MG to be used in dual-head configuration has the same intended use as the predicate device but some different technological characteristics. Bench testing showed that the safety and effectiveness of the RadiForce RX840-MG was not affected by the differences of the technological characteristics. Therefore, the RadiForce RX840-MG was determined to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Mr. Hiroaki Hashimoto
Manager
EIZO NANAO Corporation
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HAKUSAN ISHIKAWA 924-8566
JAPAN

Re: K120451
Trade/Device Name: 8MP Color LCD Monitor, RadiForce RX840-MG
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 17, 2012
Received: July 19, 2012

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: 8MP Color LCD Monitor, RadiForce RX840-MG

Indications for Use:

The RadiForce RX840-MG is intended to be used in displaying and viewing digital images including those of digital mammography for review and analysis by trained medical practitioners.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120451